UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **THE WAVE 1 CASES IDENTIFIED IN EXHIBIT A TO ETHICON'S MOTION**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE IN OPPOSITION TO ETHICON'S MOTION TO EXCLUDE THE TESTIMONY OF DUANE PRIDDY, PH.D.

Plaintiffs submit the following memorandum of law in opposition to the "Motion to Exclude the Testimony of Duane Priddy, Ph.D." filed by Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon"). Dr. Priddy's testimony should be admitted for the following reasons:

INTRODUCTION

Duane Priddy ("Dr. Priddy") has a Ph.D. in Organic Chemistry and over forty (40) years of professional experience in the plastics industry focusing on the failure of plastic products, including medical devices.[1] Dr. Priddy worked as a Principal Scientist at Dow Plastics for over thirty (30) years, where he led a team that researched all kinds of plastic oxidation and degradation to develop improved antioxidant stabilizer formulations for Dow's plastic products. He is the founder and CEO of Plastics Failure Labs, at which he performs failure analysis and other research on numerous plastic products. It is in this capacity that he consulted for American

[1] Ex. A, Priddy CV; Ex. B, Dr. Priddy Report at 1.

Medical Systems, Inc. ("AMS") in helping that pelvic mesh manufacturer understand the chemical nature of its polypropylene ("PP").[2]

Ethicon' Motion does not challenge any of Dr. Priddy's *opinions*. The Motion only challenges the exemplar testing that Dr. Priddy performed. As such, regardless of the Court's determination of the admissibility of his testing, all of Dr. Priddy's opinions should be heard by the jury in these cases. The opinions proffered by Dr. Priddy will allow a jury to understand the chemically unstable nature of the Prolene PP used in Ethicon's mesh products to treat Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP).[3]

Moreover, the testing that Dr. Priddy performed for this case—which Ethicon now challenges—is American Society for Testing and Materials ("ASTM"), an industry standard, and it is the same kind of testing and analysis that he has done throughout his career. And Dr. Priddy's testing was only conducted due to Ethicon's repeated assertion that Prolene contains a unique and special blend of antioxidants—a position that Ethicon's own experts have not dared to attempt to verify through their own testing. His testing simply further verified his opinion that the antioxidants in Prolene do not stop the Prolene from being inherently unstable. This testing stands on its own, was performed by the book, and should not be excluded.

Dr. Priddy has spent more than three decades developing and working with antioxidants to help prolong the usable life of PP and other plastics—and Prolene's formula has remained unchanged during this entire time. Dr. Priddy is especially qualified to testify about the nature of this resin and why it should not be used in this application. As such, his opinions are entirely relevant and reliable and should not be excluded.

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[2] *Id.*
[3] *Id*. at 2.

STANDARD OF LAW

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. The witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995).

The court's focus in a *Daubert* inquiry should be solely on the expert's "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Notably, "the Supreme Court itself viewed *Daubert* as a *liberalization*, not a tightening, of the rules controlling admission of expert testimony." *Cavallo v. Star Enterprise*, 100 F.3d 1150, 1158 (4th Cir. 1996) (emphasis added). Further, "exclusion is the least favored means of rendering questionable scientific evidence ineffective." *Id.*

ARGUMENT

Dr. Priddy's opinion that PP is too unstable to be used in Ethicon's SUI and POP devices is relevant to the ultimate question of liability that the jury will be asked to decide in this case, and his opinion is reliably based in the scientific method. All of Dr. Priddy's opinions are supported by his professional experience, the peer-reviewed literature, the chemical reactions involved, as well as the conclusions of Ethicon's internal oxidation studies. Moreover, as Dr. Priddy states in his report: "[t]he testing and analysis that I have done as part of my work confirms my opinions based on the scientific literature and my experience."[4] His testing did not form his opinions in this case——it only confirmed what he already knew about PP and what the literature has said about it for decades.

[4] Ex. B, Dr. Priddy Report at 2.

A. Two ASTM industry standards were employed to evaluate 10 Ethicon meshes.

Dr. Priddy used two ASTM industry standards to evaluate ten (10) exemplar Ethicon meshes. ASTM D3895 is a common test that "measures a material's resistance to oxidative decomposition."[5] This protocol was followed by Dr. Priddy to the letter and involves placing the exemplar meshes under high heat under tightly controlled conditions.[6] The results showed over 150% variance between the meshes tested, leading Dr. Priddy to conclude that "the material in different lots of Ethicon SUI and POP PP devices will degrade at varying rates."[7] Further, by applying the methods in ASTM F1980, which is the industry standard methodology for accelerated aging, Dr. Priddy found that "[t]he estimated time for depletion of antioxidants [inside the body]…is only a few months in some mesh samples."[8] These ASTM standards were employed not only because they are industry standards that Dr. Priddy has used throughout his career, but also because the methodology and evaluations done are well described and allow for anyone to repeat the exact tests performed.

B. Dr. Priddy's opinions in this case are relevant and reliable.

Dr. Priddy's opinions regarding the chemical stability of Ethicon's Prolene material are relevant and reliable. Dr. Priddy's Report and exhibits detail decades of scientific knowledge and peer-reviewed literature as support for his opinion that Prolene PP should not have been used in Ethicon's SUI and POP devices.[9] Dr. Priddy spent three decades at Dow Chemical studying ways to develop better antioxidants for plastics like PP—all of his past research informed his

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[5] Ex. B, Priddy Report at 3.
[6] *Id*.
[7] *Id*.
[8] *Id*.; Dr. Priddy also extracted the antioxidants present in these meshes after they were run through these ASTM testing conditions and found that the amount of antioxidant correlated to the variations he found in the oxidative testing, *Id*. at 13.
[9] *See* Ex. B, Priddy Report; Ex. C, Priddy Facts and Data Considered.

opinions in these cases. Prolene's chemical formula has remained relatively unchanged since before the time that Dr. Priddy first began a career studying oxidation and degradation of plastics, that alone makes his testimony relevant—and the scientific literature and decades of experience that Dr. Priddy has improving the useable life of plastics, including those used in implantable medical devices, make his testimony reliable.

C. Ethicon's arguments do not justify the exclusion of Dr. Priddy's testing.

Ethicon puts forth six reasons why it believes the Court should exclude the testing performed by Dr. Priddy. Specifically, Ethicon argues that: (1) the testing does not replicate the *in vivo* environment in which the mesh products are used; (2) the testing is unreliable and speculative; (3) Dr. Priddy failed to follow his written protocol; (4) Dr. Priddy failed to use a control in his testing; (5) that Dr. Priddy lacks a sufficient understanding of his own testing; and (6) that Dr. Priddy failed to provide statistical analysis for his test data.[10] As discussed in the following paragraphs, none of these arguments have merit.

1. The testing done followed ASTM industry standards and it is not compromised in any way—therefore, Ethicon's "*in vivo* environment" and "unreliable and speculative" arguments fail.

Dealing with these arguments in order, Ethicon's first argument—that the testing does not replicate the *in vivo* environment—while technically correct, misses the point.[11] Dr. Priddy used two ASTM standards to evaluate ten (10) exemplar meshes. The methodologies of those ASTM standards correlate to each other. ASTM D3895 describes the protocol for the "Oxidative Induction Time" ("OIT") testing performed, and the data collected from that testing was used with ASTM F1980's accelerated aging testing's protocol to determine how long the

[10] Def's Memo at 3-12. Again, the Motion does not challenge his opinions—just his testing. For this reason, Dr. Priddy should not be precluded from offering his opinions at trial regarding the use of Prolene PP in this application.
[11] Def's. Memo at 3-6.

antioxidants would protect the mesh inside the body.[12] Dr. Priddy's report correlates this *ex-vivo* high-heat testing to results in the body.

Moreover, the testing conducted by Dr. Priddy in this case is common to the industry and has even been performed by Ethicon internally. In no way is this testing meant to directly replicate the body's *in vivo* environment—indeed, it was performed at several hundred degrees above human body temperature. Rather, the testing was performed on exemplar meshes to ascertain what, if any, variance there was in the meshes' stability and the most efficient way to do this was under high heat. The data collected from this testing was then correlated using another ASTM standard to determine how long the antioxidants would last inside the body.[13] All of which was done with industry-standard, repeatable, scientifically sound ASTM methods.

Similarly, the Motion argues that Dr. Priddy's testing is "unreliable and speculative" because of the nature of the testing done, but the point is the same—the testing is common to the plastics industry and it shows that the antioxidants in Prolene do not retard degradation for long. Ethicon is free to ask Dr. Priddy if he followed the ASTM standards or what the testing entailed in front of a jury—but these kinds of questions go "to the weight and not the admissibility of the evidence." *See In re: DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*, No. 3:11-MD-2244-K 2104 U.S. Dist. LEXIS 97798, at *45 (N.D. Tex. July 18, 2014). Dr. Priddy's ASTM testing is repeatable, done on a large sample size, focused on the scientific method, and it was performed on pristine meshes provided by Ethicon. It should not be excluded.

2. Ethicon creates false issues regarding Dr. Priddy's written protocol, controls, understanding of his testing, and the need for a statistical analysis.

[12] *See* Ex. B, Priddy Report at 3.
[13] *See* Ex. B, Priddy Report at 2-3.

Ethicon asserts that Dr. Priddy failed to follow a written protocol, that Dr. Priddy failed to use a control in his testing, that Dr. Priddy lacks a sufficient understanding of his own testing, and that Dr. Priddy failed to provide statistical analysis for his test data—but these attempts to undermine Dr. Priddy's testing have no legitimacy.

First, Dr. Priddy followed ASTM standardized testing and he provided that written protocol in a step-by-step description of how it was done to the defense—there is absolutely no evidence that he deviated from the ASTM protocol.[14] As such, Ethicon's claim that he did not follow a written protocol is simply false.

Second, the Motion argues that since Dr. Priddy did not run pure PP without antioxidants as a control through the ASTM protocol, then the results are useless. This argument is also baseless—because there was no need for him to do so. This ASTM testing has been done on pure PP for decades. The data is known, and it is standardized in textbooks, which is what Dr. Priddy turned to for his value for the control.[15] This material has been extensively studied for many decades in all manner of applications and there is no need to reinvent the wheel for every test that is run when the values are already known.

Ethicon also argues that the testing should be excluded because Dr. Priddy did not understand it well enough.[16] There is simply no bases for such a claim. Dr. Priddy spent his career performing tests like the one he did for his report. He chose this testing based on the fact that it was standard plastic-industry practice. The mere suggestion that Dr. Priddy did not understand the testing performed should not preclude his testing from trial. And if Ethicon

[14] *See* Ex. D, Dr. Priddy OIT Written Testing Procedure (included in Exhibit 2 of Dr. Priddy Deposition 3/8/2016).
[15] *See* Ex. B, Dr. Priddy Report at 3-4, FN. 3-6; *see also* Ex. E Dr. Priddy Deposition, 3/8/2016, 84:2-13.
[16] Def's Memo at 11-12.

believes that there are inconsistencies between the testing and Dr. Priddy's understanding of it or its findings, that is merely an issue for cross examination.

Finally, Ethicon argues that the testing should be excluded because Dr. Priddy did not perform or provide a statistical analysis to support his findings. That argument, however, is a logical fallacy given the nature of meshes that were involved in this testing. The purpose of a statistical analysis is to rule out the possibility that the results were influenced or due to problems with the sample size used in the test. But the SUI and POP meshes at issue are all knit from Prolene monofilaments and there is no way for the Plaintiffs to track when those monofilaments were extruded or how long they were in storage.[17] Plaintiffs can only track the lot number of the meshes examined, but those meshes could be made out of dozens, maybe even hundreds, of different monofilaments spools that were knitted together to make a single mesh. But the lot number of the meshes Dr. Priddy examined tells us nothing about how the monofilaments that make up these meshes were stored or of the conditions of the actual extrusion itself. There is simply no way to draw a statistical significance from this kind of data—and that was not what Dr. Priddy was trying to do in this case.[18]

The Motion is asking for the impossible, yet it does not argue that Dr. Priddy's sample size was not large enough, it just finds fault where no blame can fall on Dr. Priddy. He found 150% variance in the stability of the 10 meshes that he examined. He is not opining that there is a certain amount of variation in the stability of those meshes that would be acceptable—it is his opinion that Prolene PP is too unstable to use in this application, and this 150% variance in when the stabilizers were depleted confirms that opinion. None of his opinions relate, in any way, to statistical probability or how one mesh will be more likely to oxidize than another—and the

[17] Ex. F, "Prolene Resin Manufacturing Specifications."
[18] *See* Ex. E, Dr. Priddy Deposition 3/8/2016, P.39:21-40:7.

underlying data necessary to make those determinations has never been produced by Ethicon in this litigation.

D. Dr. Priddy's testing is distinguishable from this Court's previous exclusion of expert testing.

While Ethicon is correct that this Court excluded the opinions of Drs. Mays, Barker, and Dunn in the past,[19] Dr. Priddy's testing stands apart from those rulings. First, the Motion points out that both Dr. Priddy and Dr. Mays conducted testing which involved exposing mesh to elevated temperatures, well above the temperature of the human body.[20] But in excluding the opinions of Dr. Mays, the Court found that he "produced certain results while testing polypropylene at very high temperatures," and "then somehow concludes that the same results will occur inside the human body at much lower temperatures, without providing any explanation or support for his opinion."[21] The Court found that "Dr. Mays has failed to connect his TGA results to the pertinent inquiry, which is whether the [mesh] degrades inside the human body."[22] Here, Dr. Priddy *does* explain how his testing correlates to the human body. Dr. Priddy's report connects the testing to how long the antioxidants would last after implantation using an industry-accepted standard and protocol.[23] Ethicon's argument that Dr. Priddy's testing must be excluded simply because Dr. Mays's testimony was previously excluded ignores this controlling distinction.

Similarly, this Court excluded Dr. Barker's and Dr. Dunn's testing because the testing they performed did not have an adequate sample size to create a statistical significance.[24] Here, however, Dr. Priddy's sample size was 10 meshes—and Ethicon does not even try to attack the testing based on sample size. Instead, Ethicon argues that Dr. Priddy should have provided a

[19] Def's Memo at 6.
[20] *Id.*
[21] *Frankum v. Boston Sci. Corp.*, No. 2:12-cv-00904 2015 U.S. Dist. LEXIS 57251, at *46-47 (S.D. W. Va. May 1, 2015) (emphasis added).
[22] *Id.* at *47.
[23] Ex. E, Dr. Priddy Deposition 3/8/2016, at 24: 15-25:3.
[24] *Mathison v. Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 U.S. Dist. LEXIS 59047, at *68 (S.D. W. Va. May 6, 2015); *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 546-547 (S.D. W. Va. Oct. 29, 2014).

statistical probability based on the data collected. As explained above, there is no reason (or way) for Dr. Priddy to create such a probability here. It is Dr. Priddy's opinion that the Prolene material is too unstable for this application, and the test results confirm that opinion.

E. Dr. Priddy will not Testify Regarding Ethicon's Knowledge, State of Mind, or Corporate Conduct

Ethicon correctly points out that this Court has previously disallowed experts to testify regarding a corporation's knowledge or state of mind.[25] Dr. Priddy does not intend to do so in these cases. However, as this Court has previously ruled: "an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions."[26] Dr. Priddy only intends to testify as to Ethicon corporate documents at trial for the purpose of explaining how the results of Ethicon's internal studies are consistent with his opinions in this case.

F. Dr. Priddy does Not Intend to Testify Regarding Clinical Complications Associated with the Prolene in Ethicon's Mesh Products

Ethicon's argument that Dr. Priddy is not qualified to testify regarding the clinical complications associated with the Prolene in Ethicon's mesh products seeks to confuse the issues in this case. Dr. Priddy's opinions in this case are simple and straightforward: Polypropylene material should not have been used in Ethicon's SUI and POP devices because of the unstable chemical nature of this product.[27] Dr. Priddy will defer to other experts in this case to speak to the clinical complications of degradation.

[25] Def's memo at 13-14.
[26] *Huskey v. Ethicon., Inc.*, 29 F. Supp. 3d 691, 702-703 (S.D. W. Va. 2014).
[27] Ex. B, Dr. Priddy Report at 2.

CONCLUSION

For the reasons stated herein, Plaintiffs respectfully request that the Court DENY the defendants' Motion to Exclude the Testimony of Duane Priddy, Ph.D. in its entirety.

This 9th Day of May, 2016 By: /s/ Edward A. Wallace

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016 I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

By: /s/ Edward A. Wallace